

JAN 22 2001

K003341

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
For Emit® 2000 Tobramycin Assay**

**I. Manufacturer and Contact Information:**

Manufacturer: Syva Company - Dade Behring Inc.  
20400 Mariani Avenue.  
Cupertino, CA 95014

Contact Information: Paul Rogers  
Syva Company  
3403 Yerba Buena Road  
San Jose, CA 95161-9013  
Tel: 408-239-2000

**II. Device Classification Name:**

The Clinical Chemistry and Clinical Toxicology Devices Panel have classified "Tobramycin Test System" as Class II.

**III. Intended Use:**

Emit® 2000 Tobramycin Assay is a homogeneous enzyme immunoassay. The assay is intended for use in the quantitative analysis of tobramycin in human serum or plasma.

**IV. Device Description and Characteristics:**

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

The Emit® 2000 Tobramycin Assay is a homogeneous enzyme assay intended for use in quantitative analysis of tobramycin in human serum or plasma. The Emit® 2000 Tobramycin Assay and Calibrators has been found to be equivalent to the predicate device: Emit® Tobramycin Assay (K874223) with regard to intended use, assay sample, and overall performance characteristics.

Specificity: Compounds, whose chemical structure would suggest possible cross-reactivity or other therapeutics concurrently used, when tested on the Emit® 2000 Tobramycin Assay, did not interfere at the levels tested.

Comparative Analysis: The Emit® 2000 Tobramycin Assay and Calibrators showed excellent correlation to the predicate method. The comparative analysis to the predicate method resulted in a correlation of 0.997 with a slope value of 0.934.

Precision: A Precision study was performed and the Emit® 2000 Tobramycin Assay demonstrated acceptable within-run precision with coefficients of variation (%CV) ranging from 1.2% to 4.5% and acceptable total precision with coefficients of variation (%CV) ranging from 1.7% to 4.8%. An additional within-run precision study was done at 0.6 µg/mL. The coefficient of variation (%CV) of 4.4%.

**Spike Recovery:** Recovery from 10 levels of spiked tobramycin was evaluated for Emit® 2000 Tobramycin assay. The overall average recovery versus nominal was 98.2%.

**Sensitivity:** The sensitivity level of the Emit® 2000 Tobramycin Assay is 0.2 µg/mL tobramycin. This level represents the lowest measurable concentration of tobramycin that can be distinguished from 0 µg/mL with a confidence of 95%.

**Endogenous Interference:** Average recovery compared to control samples was studied separately to assess endogenous interference due to bilirubin, hemoglobin, and triglycerides in the Emit® 2000 Tobramycin assay. Average recoveries were 99.2, 101.7, and 97.2% for bilirubin, hemoglobin, and triglycerides, respectively. There was no effect on the accuracy of the results.

**High Sample Dilution:** High sample dilution was evaluated by diluting a high-spike sample four different ways. Separate 1:2 and 1:3 dilutions with Emit® 2000 Tobramycin Calibrator 0, and 1:2 and 1:3 dilution with water of each spike sample was assayed. The recovery values ranged from 95.5 to 98.4 percent. There was no significant effect on the accuracy of the results.

**Anticoagulants:** The effects of the anticoagulants K<sub>3</sub>EDTA, sodium heparin, sodium citrate and oxalate/fluoride plasma as compared to serum was tested on the Emit® 2000 Tobramycin Assay. Average recovery, compared to the serum control was 100.0 to 100.7 percent.

#### **V. Substantial Equivalence:**

In conclusion, Syva Company – Dade Behring Inc. considers the Emit® 2000 Tobramycin Assay and Emit® 2000 Tobramycin Calibrators to be substantially equivalent to the Emit® Tobramycin Assay (K874223) and Emit® Tobramycin Calibrators with regard to intended use, assay sample, and overall performance characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 22 2001

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Paul L. Rogers  
Senior Manager, Regulatory Affairs  
Dade Behring Inc.  
3403 Yerba Buena Road  
PO Box 49013  
San Jose, California 95161-9013

Re: K003341  
Trade Name: Emit® 2000 Tobramycin Assay  
Emit® 2000 Tobramycin Calibrators  
Regulatory Class: II  
Product Code: KLB, LDO, DLJ  
Dated: December 22, 2000  
Received: December 26, 2000

Dear Mr. Rogers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, **subject** to the general controls provisions of the Act. ~~The general controls provisions of the Act~~ include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.

Director

Division of Clinical Laboratory Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): K003341

Device Name: Emit® 2000 Tobramycin Assay  
Emit® 2000 Tobramycin Calibrators

**Indications for Use:**

The Emit® 2000 Tobramycin Assay is a homogenous enzyme immunoassay intended for *in vitro* diagnostic use in the quantitative analysis of tobramycin in human serum or plasma. Monitoring tobramycin concentrations in serum, along with careful clinical assessment, is an effective means of ensuring adequate therapy.

*Sean Coogan*  
(Division Sign-Off)  
Division of Clinical Laboratory  
510(k) Number K003341  
510(k) Number

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)